CRT 2000®

THERMOGRAPHIC SYSTEM

Product Manual

eidam
DIAGNOSTICS CORPORATION

Leader in innovative health solutions.

CRT 2000 Thermographic System Product Manual (rev. 7.10)

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Introduction

Important

Please read the entire Product Manual before using the equipment.

This Product Manual describes the installation, usage and maintenance of the CRT 2000® Thermographic System. It is complemented by the CRT 2000® Technician's Handbook, which provides additional details for conducting a CRT exam.

Trademarks and other Information

All company, product, and trade names referred to in this manual are trademarks of their respective companies. Eidam® and CRT 2000® are registered trademarks of Eidam Diagnostics Corporation. Microsoft® and Windows® are registered trademarks of Microsoft Corporation.

Symbols Used

CE XXXX	This product conforms to the EC-Directive for medical products. (93/42/EWG).		
	Please read user manual before starting		
IPX0	The device is not water resistant.		
	Manufacturer symbol		
	Applied Part Type BF1		
Device Number:	SN: xx.v.yy.zzzz	xx.v:	internal code number for product type and version.
		yy:	Production Year
		zzzz:	Serial Number

[1] Applied part warrants protection against electric shock through norm-conform restriction of leakage currents (Type B); applied part is isolated (floating) (Type F)

Safety Instructions

The CRT 2000® Thermographic System is a medical device to be used exclusively for measuring temperatures on the patient's skin. Any other use is strictly prohibited.

Under no circumstances should a user attempt to disassemble any part of the CRT 2000® including the sensor or to make alterations to the equipment.

Do not insert sensor into body cavities.

Inappropriate use, storage or exertion of influence may lead to functional interference or damage of the equipment.

In case of smoke emission, an abnormal smell or atypical sounds, immediately power off the equipment and disconnect the power cable.

If there is condensation in or on the equipment, do not use the equipment. Condensation takes place in the form of water droplets or moisture: for example, exposing the equipment to extreme temperature variations can lead to operational disturbances or errors.

Disclaimer

The science and medicine of contact regulation thermography are beyond the scope of this manual. This manual details only the usage of the equipment and software, not the interpretation of data or any scientific reasoning.

This information and any other information provided, published, or made available through Eidam Diagnostics Corporation is for educational or informational purposes only: it is not intended to replace the services of a physician or other accredited health-care provider, or to be or act as a substitute for professional medical advice, care, or treatment. You should not rely on or use any such information for determining the state of your health; for diagnosing or treating a medical or health condition; or as a substitute for personal medical attention, diagnosis, or hands-on treatment. You should consult a physician in all matters relating to your health, and particularly in respect to any symptoms that may require diagnosis or medical attention.

Eidam Diagnostics Corporation makes no representations or warranties with respect to any information provided, published, or made available through the CRT 2000® Thermographic System, and is not liable for any direct or indirect claim, loss, or damage resulting from use of or reliance on any information provided, published, or made available through Eidam Diagnostics Corporation or the CRT 2000® Thermographic System.

Eidam EasyStart

Introduction

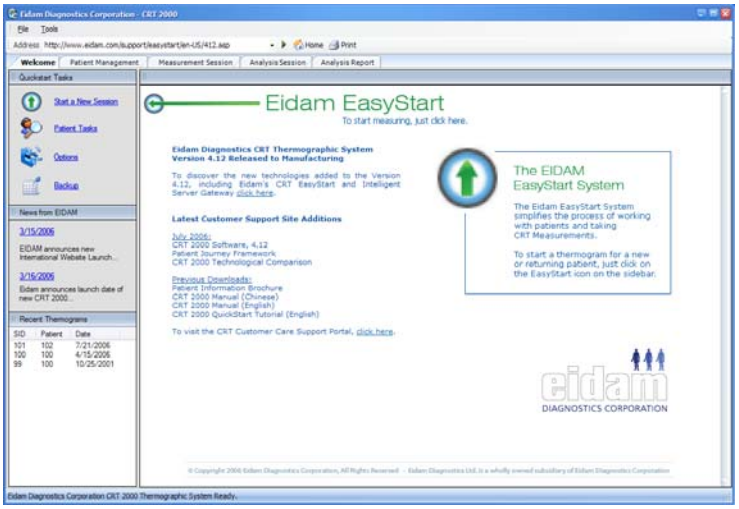
This tutorial describes the process of adding a patient, taking a measurement, and viewing a Thermogram. It also explains some of the basic terminology specific to the CRT 2000®.

Before beginning, ensure that the probe is connected and that an internet connection is active.

With the CRT turned on, press and hold the CRT Sensor test button for four seconds. You will hear a beep, followed by a double beep, and the LCD display on the front of the CRT will read, “Waiting to Initialize”. The CRT is now ready for use.

Start the CRT software by double-clicking the program icon on the desktop.

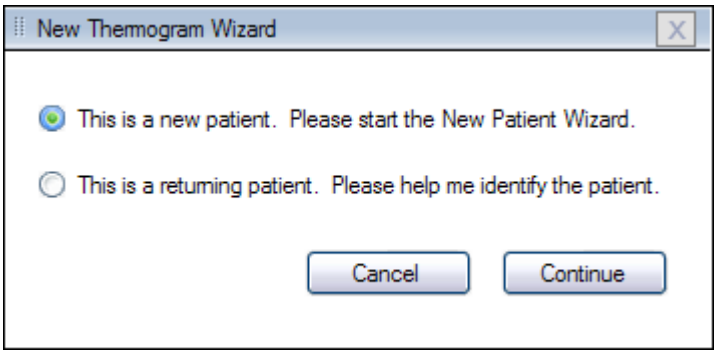
EasyStart Welcome Screen


Eidam EasyStart
To start measuring, just click here.
Eidam Diagnostics CRT Thermographic System Version 4.12 Released to Manufacturing
The EIDAM EasyStart System
Latest Customer Support Site Additions
DIAGNOSTICS CORPORATION

The Eidam EasyStart welcome screen simplifies the process of working with patients and conducting CRT sessions. The welcome screen also identifies any new updates and Customer Support site additions available for download.

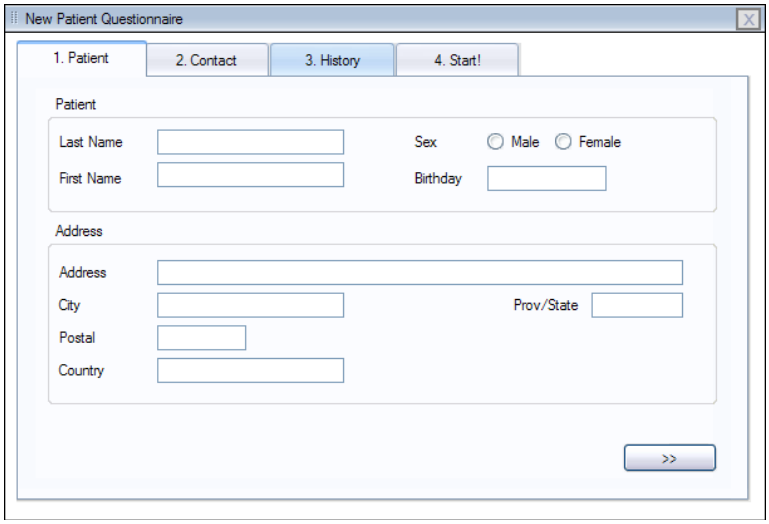
To start a Thermogram for a new or returning patient, click on the EasyStart icon on the sidebar.

New Thermogram Wizard


New Thermogram Wizard
This is a new patient. Please start the New Patient Wizard.
This is a returning patient. Please help me identify the patient.
Cancel
Continue

The New Thermogram Wizard allows a technician to easily add a new patient, or access an exiting patient.

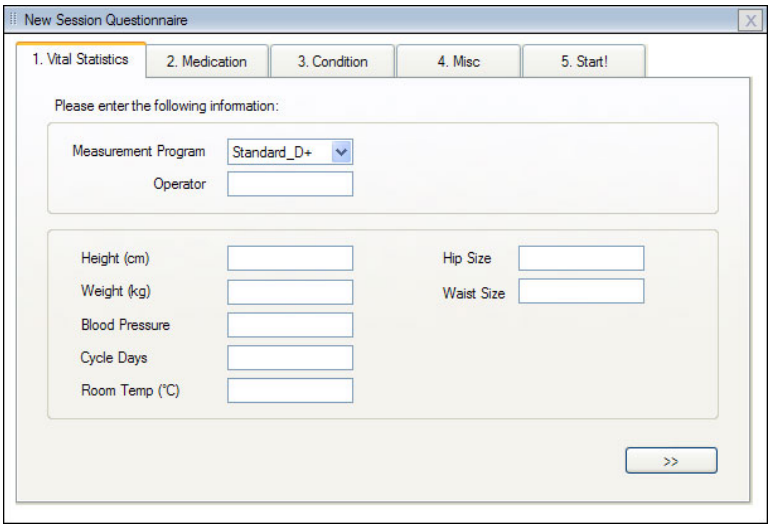
For this tutorial, select “This is a new patient” and then click Continue. A **New Patient Questionnaire** window will appear.



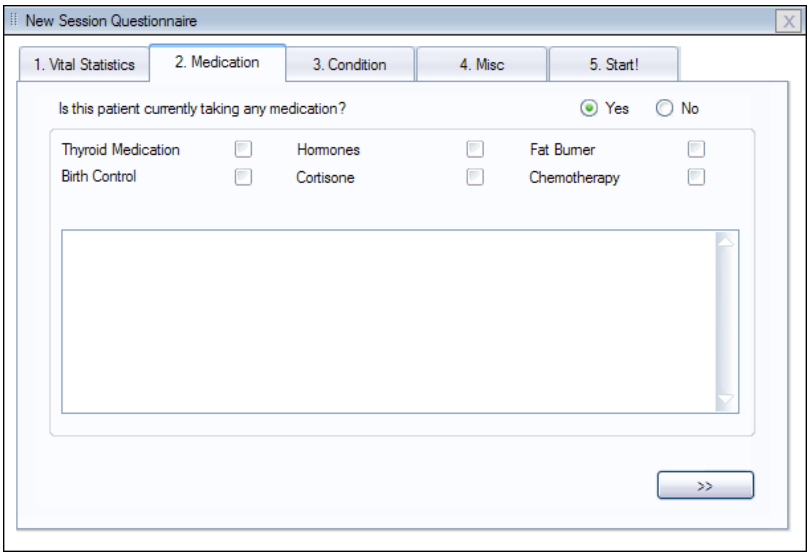
Complete each tab of the Patient Questionnaire, taking care to complete the patient history as accurately as possible.

Once the Patient Questionnaire has been completed, the **New Session Questionnaire** window will automatically start.

1. Complete the **Session Questionnaire**.



3. Each section must be completed in order to proceed. Select "Yes" if any of the conditions for a section applies, and check off specific conditions; otherwise select "No". Complete this questionnaire as accurately as possible.

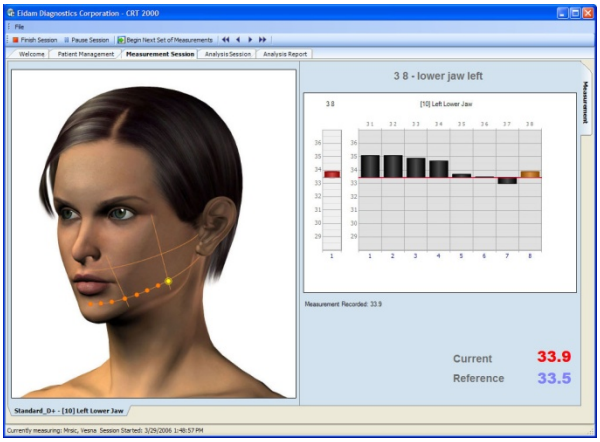


4. Click **OK.**

Performing the Measurement

A CRT *Measurement Session* consists of a *First Reading*, during which the patient progressively disrobes, a 10 minute cooling period, followed by a *Second Reading*. Each Reading consists of 119 *Measurement Points*.

After completing the Session Questionnaire, the Measurement screen will appear, with a visual guide to the left, and measurement data to the right.



To take measurements:

1. Touch the sensor to the patient's skin, ensuring that it is perpendicular to the surface. An audible beep will indicate that the sensor has made contact, and a double beep follows shortly to indicate that a temperature reading has been taken successfully.
2. To set the reference temperature, the first point must be re-measured at least once. The software will continue to ask that this point be re-measured, until there are two consecutive measurements with a temperature difference of 0.1°C or less (this applies *only* to the first point).
3. Measure points as indicated by the visual guide to the left, and detailed in the Technician's Handbook.
4. To re-measure a point, click on the left arrow in the toolbar.
5. For men, the breast regions are optional.

   *Note: for men, click **Begin Next Set of Measurements** after the lower abdomen has been measured.*

6. When all of the points of the First Reading have been measured, a 10 minute timer will appear. After 10 minutes have passed, take the Second Reading (re-measure all of the points).

7. When all of the points have been measured a second time, the measurement session is complete.

   *Note: If the breast is not being measured, click **Finish Session** button once the other points have been measured.*

View the Results

Once the Measurement Session is complete, the software opens **Patient Management**. The Thermogram may now be viewed for analysis:

1. Click on the session that was just recorded, at the top of the Patient List to the left.
2. Click Load Analysis.
3. Click OK to send the session to Eidam Servers for analysis.
4. The Thermogram will automatically load once the analysis is complete.
5. To view the detailed Analysis Report click on the Analysis Report tab.

This concludes the CRT EasyStart Tutorial.

Equipment Installation and Maintenance

Safety Inspection and Calibration

The CRT 2000 Sensor must be calibrated at least every two years to ensure device accuracy. The sensor must be calibrated by an Eidam Technical Support Centre. Please refer to the Technical Support section of this manual to locate a service centre near you.

Serial Number and License Information

All licensing and serial number information is affixed on a label on the left panel of the CRT Core Unit. In some cases, such as a software upgrade, you may need to re-enter this information.

Installation

The CRT 2000® ships with Microsoft Windows XP and the CRT 2000 Measurement and Analysis Software preconfigured. If you are unfamiliar with connecting computer equipment, please call Eidam technical support.

To connect the CRT 2000®, follow these steps:

1. Unpack the two boxes containing the CRT Thermographic System. They should include:
    - CRT 2000® Thermographic System Core Unit
    - CRT Skin Surface Temperature Sensor

- CRT 19” Widescreen LCD Display
- 2 Power Cables (1 for display, 1 for Core Unit)
- VGA Video Cable
- Mouse and Keyboard
- Microsoft Windows XP License
- Product Documentation Manual
- Technician’s Handbook

2. Connect the mouse and keyboard, matching the color coded connectors to the Core Unit.
3. Connect the CRT Sensor to the Core Unit, by gently pressing the metal connector into the plug at the front of the CRT 2000®. The connector is keyed, such that the red dot faces up and matches the indentation on the connector (See section below, *Sensor*).
4. Connect the VGA Video Cable from the computer to the monitor.
5. Connect the supplied Power Cables from the computer and monitor to AC power.
6. Connect the Internet as per your Internet Service Provider’s instructions. If you have high speed Internet, such as a cable modem or ADSL, you will need most likely need to connect their supplied Ethernet cable, which looks similar to wide telephone connector, to the matching receptacle at the back of the CRT Core Unit.
7. Power on the CRT Thermographic System by pressing the power switch on the front panel.

8. Run the CRT Sensor Self Test by pressing and holding the metal button on the sensor until hearing a double-beep. Please read the section ***Sensor*** for more information.

Cleaning / Disinfection

Turn off the unit and disconnect the power cable before cleaning.

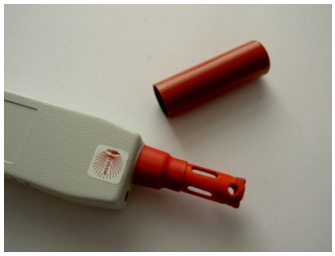
The basic unit can be wiped carefully with a soft, lint-free cloth as needed. Isopropyl Alcohol may be applied to a cloth. Do not use abrasive detergents, aggressive cleaning agents such as acetone, as this will damage the polymer coatings.

Very Important: Water must not enter the unit.

Cleaning / disinfection of the Sensor:

The sensor should be carefully wiped with a soft, lint-free cloth as required. Soft cleaning detergents, such as a gentle dishwashing soap may be used.

Do not use abrasive detergents, aggressive cleaning agents; this will damage the polymer coatings. Should any liquids enter the sensor, allow at least 2 hours time for the sensor to dry completely.



You can sterilize the sensor tip by immersing it for maximum one centimeter into a container of non-aggressive disinfecting agent (ie. 70 % Alcohol, 0.5% Chlorhexidin and water).

Standard disinfecting agents are too aggressive and may dissolve the mesh at the tip of the sensor. Allow several minutes time for the sensor to dry completely before reusing it.

The sensor cannot be autoclaved or sterilized with hot air.

Environmental Issues and Safe Disposal

All components of the equipment described including the packaging are designed to maintain a high degree of environmental friendliness. All parts of the described device can be separated and recycled or correctly disposed of by companies offering special waste disposal services. Defective products or products no longer used can be returned to the manufacturer for disposal.

Sensor

The sensor is connected to the main unit with a special 7-pin plug. To connect the sensor, find the red alignment marking on the 7-pin connector. Face the red alignment dot in the same direction as the notch on the connector and gently insert.

Removing the Sensor:

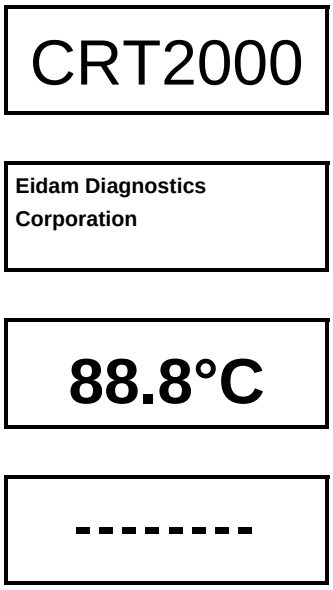
To disconnect the sensor from the CRT 2000®, pull the ribbed cover on the connector back. The connector will unlock, allowing the sensor to be removed.

Important Note for Use of the Sensor:

While the sensor is in contact with the patient, do not move the sensor in a side to side motion. Doing so may damage the sensor.

Self Test Instructions

When the CRT Core Unit is powered up, the following messages will appear on the CRT Core Unit LCD:



Test Reading

Once the above internal checks have been successfully completed, the following message will appear on the display screen:

Please press the test button

Press the silver test button on the back of the sensor. **Do not release the button until you have heard the second, double beep**. A successful test reading is indicated by the following message on the display screen (34.2° C and 34.4°C are acceptable test readings also).

34.3°C

Test reading o. k.

The above information will appear on the display after a brief pause, followed by:

Waiting to Initialize

The CRT 2000® is now ready.

Errors in the Test Reading Procedure

If the following information appears on the display screen after pressing the test button:

Test reading too low

This may mean the Test Button was released before the second double beep. Press the test button again and wait for the double beep**.**

If the measurement procedure starts automatically or the following message appears, it is likely that the sensor is defective. Please contact Eidam's Technical Support immediately.

Test reading too high

Before the message “Test Reading too low/high” is displayed, the test reading measurement will be briefly displayed**. Please make note of this temperature reading and contact Eidam’s Technical Support immediately**

Determining the Firmware Version

The following message will appear briefly on the display screen if the test button is held down while the ***CRT-2000®*** is being powered up:

(Version number and date are dependent upon the unit and version of the unit):

Version 41.4U
of 27.09.2006

Software Documentation

Starting the Software

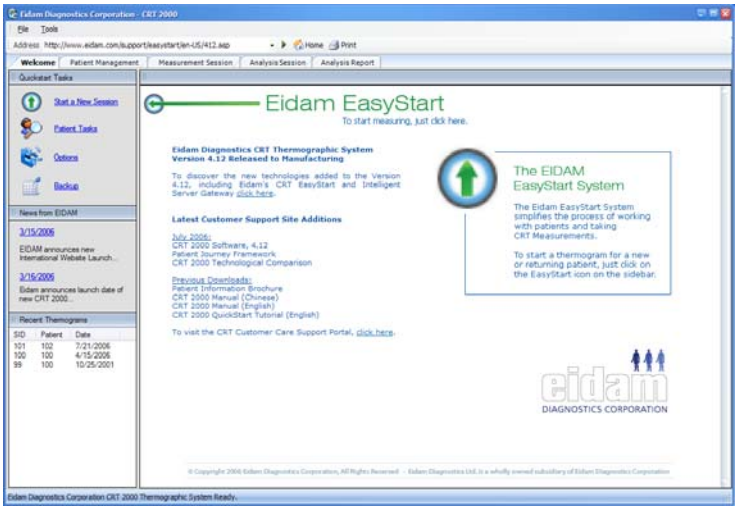
Before running the CRT Measurement and Analysis Software, ensure that the CRT Sensor has been connected properly, and that an Internet connection is available.

Very Important: An active Internet connection is needed to operate the CRT 2000® Thermographic System

Double click the CRT Icon on the Windows XP Desktop to start the software.

Welcome Screen

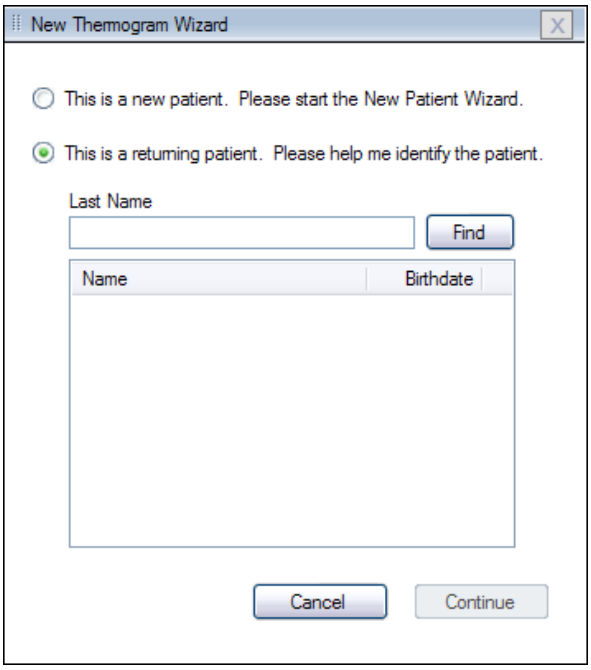
Once the software has successfully loaded, the Eidam EasyStart screen will appear:



This indicates that the CRT Thermographic System has started, and that the equipment has passed self-tests.

To access different areas of software functionality, click on the QuickStart Tasks to the left, or on one of the Tabs above (for instance, Patient Management).

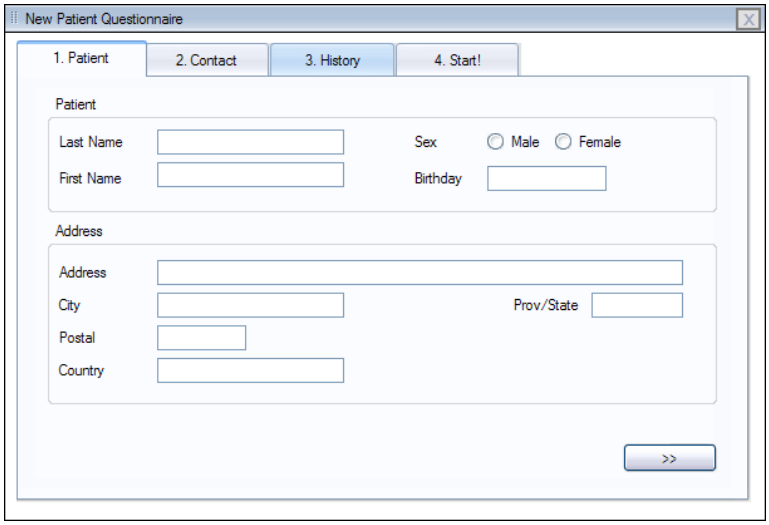
Eidam EasyStart



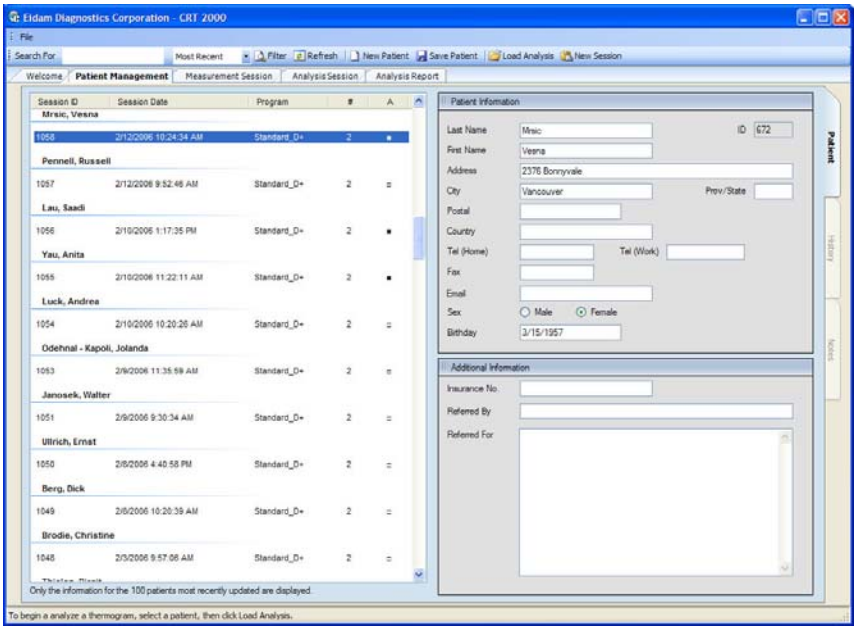
Eidam EasyStart allows a technician to easily add a new patient or access an existing patient.

For new patients, the New Patient Questionnaire guides the technician through a series of questions to add the patient. Ensure that the questionanaire is completed as accurately as possible.

For returning patients, entering the last name will recall all patients whose last name matches any part of the search criteria. For example, “Eldon” will list Eldon, Eldonson, and Sheldon.



Managing Patients



The Patient Management tab is divided into two panels: the Patient List on the left and the Patient Information Panel on the right.

Patient List: The list of patients names, records of their measurements sessions in date order.

Patient Information Panel: Patient personal information including health records are displayed here.

Patient List

This window lists patients and measurement sessions recorded. There are five parameters for obtaining useful patient information about the sessions.

Session ID: Shown in this column is the ID number given to each measurement session.

Session Date: The date and time of the measurement session.

Program: The program which was used for the measurement.

#: The number of measurements conducted in the session.

A: A column consisting of a single checkbox for each measurement session. Black colored checkbox shows the session data has already been analyzed by the server, and the Thermogram and analysis report are available to be viewed.

A blank checkbox indicates the data has not yet been sent to the server for analysis.

Clicking on a session gives information about the patient in the Patient Information Panel.

Adding, Deleting, and Updating Patients

Add a New Patient

To add a new patient, click **New Patient** on the Toolbar. In the popup window, fill out the patient's first and last name, then click OK.

Entering Patient Data

The *Patient Information* window contains the patient's personal information, medical history, and the physician's notes.

To save changes click **Save Patient** on the toolbar.

If the symbol appears, a required field has been omitted

Update Patient Data

To update an existing patient, first click on any entry below their name in the Patient List.

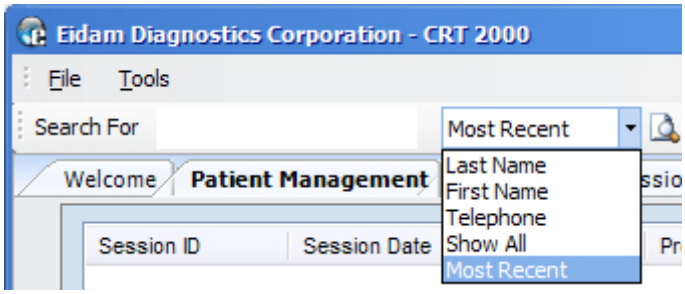
Deleting a Patient or Measurement Session

Patients can only be deleted if they have no measurement data. Delete a patient by right-clicking the row underneath the patient's name, reading, "None", and then left-clicking **Delete Patient**.

To delete a patient who has measurement sessions, you must first delete all associated measurement sessions by right clicking the measurement session, and left-clicking **Delete Session**.

Deleting a patient or measurement session is a permanent operation and cannot be reversed.

Finding a Patient



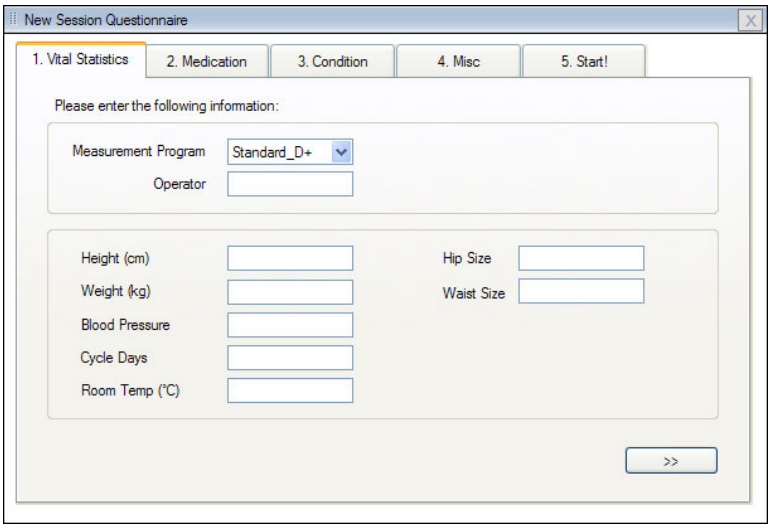
To find an existing patient, you can use the Search function in the toolbar. Select a search type in the dropdown, enter criteria to narrow the search, and then click on "Filter" to search the patient database.

Entering Measurement Data

Adding a New Measurement

To begin a new Measurement Session, select a customer, and then click on the New Session icon in the Toolbar.

The following wizard will appear, guiding you through the process:



Some of the fields are required. If you miss one of these fields, the CRT will advise you with a symbol.

Follow the wizard, and which will take you to the measurement process.

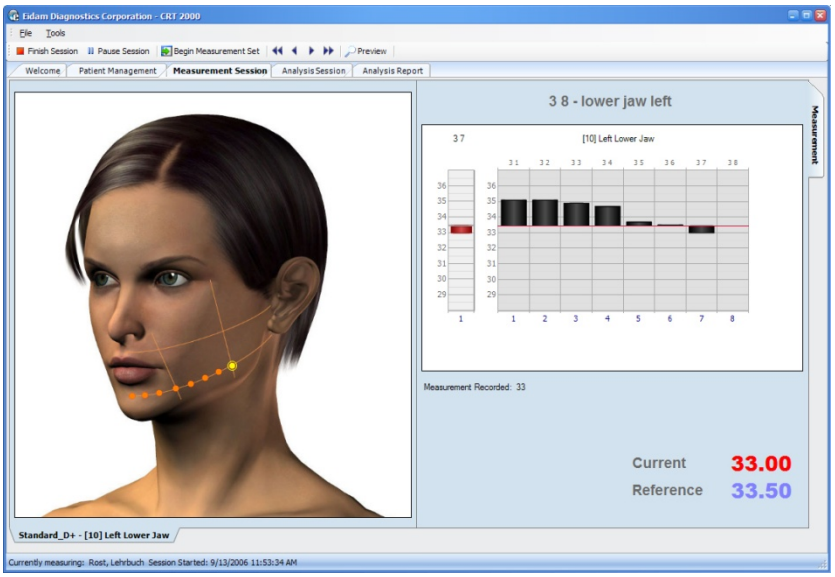
Note:

Two measurement programs are available:

1) Standard D+ Program for adults,
2) Child D+ Program for children.

Taking measurements

Once the questionnaire has been completed, the following screen will appear:



The left panel pictures a model showing the position of each measurement point.

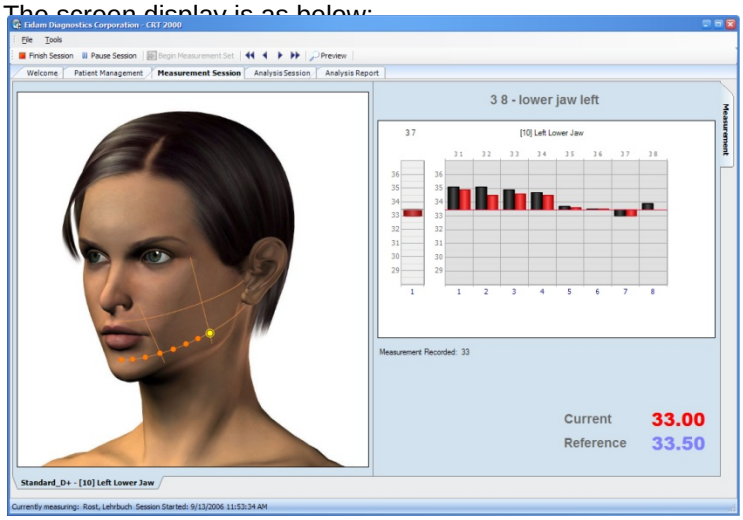
The right panel contains a temperature graph showing the measured temperature of each point. Above is the measurement point description. Below the temperature graph is the progress of the measurement.

Click the toolbar button **Begin Measuring**. Put the probe perpendicularly to the skin to measure the first reading point (Glabella point). The first beep indicates the beginning of the measurement. The second beep indicates the end of reading (double beep after Version 35). Remove the probe from the reading point.

To set up the reference value axis, you need to measure the same point twice. The difference between the readings must not exceed 0.1° C. If the difference is higher, repeat the procedure till the measurements do not exceed 0.1° C.

The first sets of readings are for dental readings. The arrow buttons in the toolbar will now be activated.

The screen display is as below:



The **Measurement Session** tab shown above will display during a measurement session. This tab will show reading position with its assignment points along with the numbers and positions of the points in the current set of readings. The thermogram of the current set of readings will also be on display.

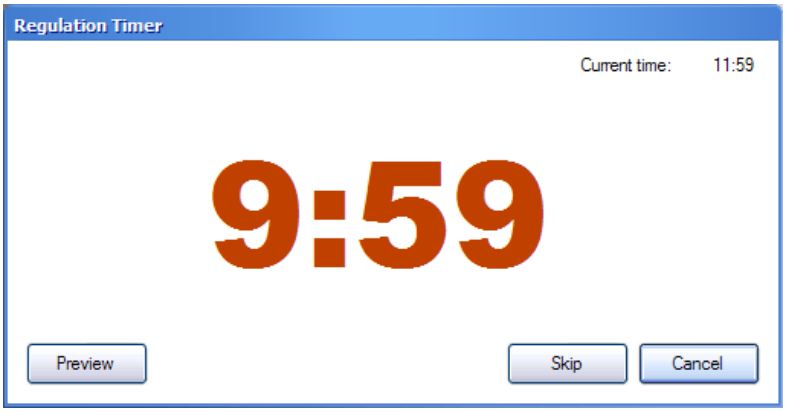
Clicking on one of the arrows on the toolbar selects the current measure point. For example, if a point was measured incorrectly, the back arrow may be clicked to re-measure this point. Clicking on one of the double-arrows (◀◀ or ▶▶) moves the current point to the previous or next measurement area.

When all measurements have been taken, click on **Finish Session**.

Pause Session stops the sensor temporarily from taking measurements. To resume the measurement session, click on **Begin Measurement**.

Begin Next Set of Measurements ends the current set of measurements and begins the next set of measurements.

When a new Measurement Set is started a timer window will open.



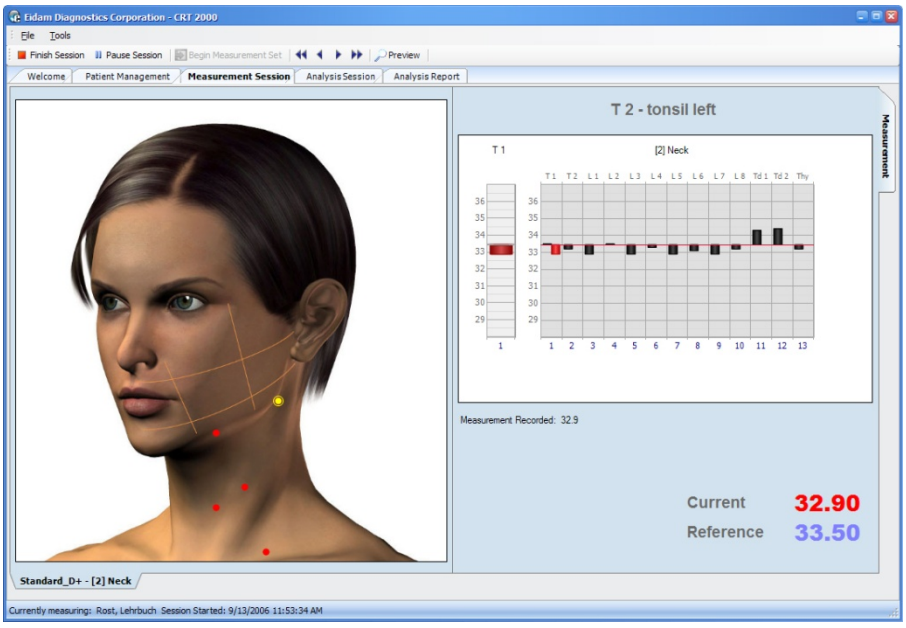
A measurement session consists at least two sets.

The first Measurement Set is charted with black bars. The second set is charted with red bars. On CRT units supporting a third or fourth measurement, the third set will be charted in green and a fourth set is charted with blue bars.

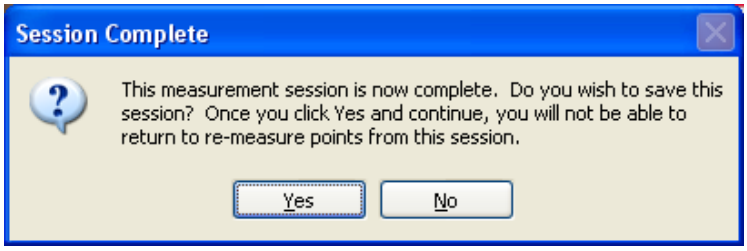
The preview button on the timer window gives a preview of the thermogram.

The skip button, once clicked, will skip the 10 minute timer altogether.

The illustration below shows the second reading in progress:



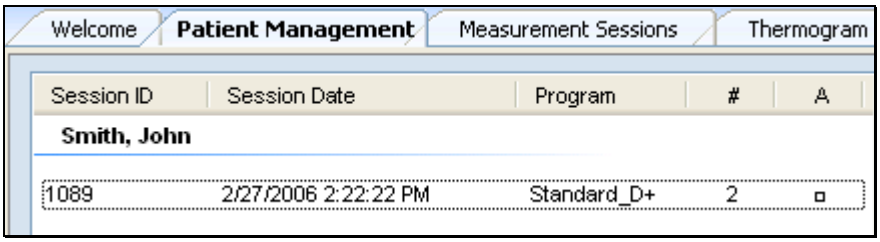
After completion of the second measurement the following dialog window appears:


Session Complete
This measurement session is now complete. Do you wish to save this session? Once you click Yes and continue, you will not be able to return to re-measure points from this session.
Yes
No

Clicking on **Yes** will complete the measurement and will save the data..
Clicking on **No** will allow measurement points to be re-measured.

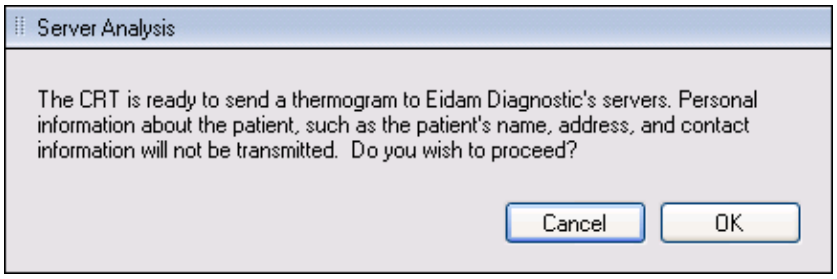
Submitting Session for Analysis

Once the measurement session is complete, the software returns to Patient Management screen. The session information in the patient records list will now look like this:



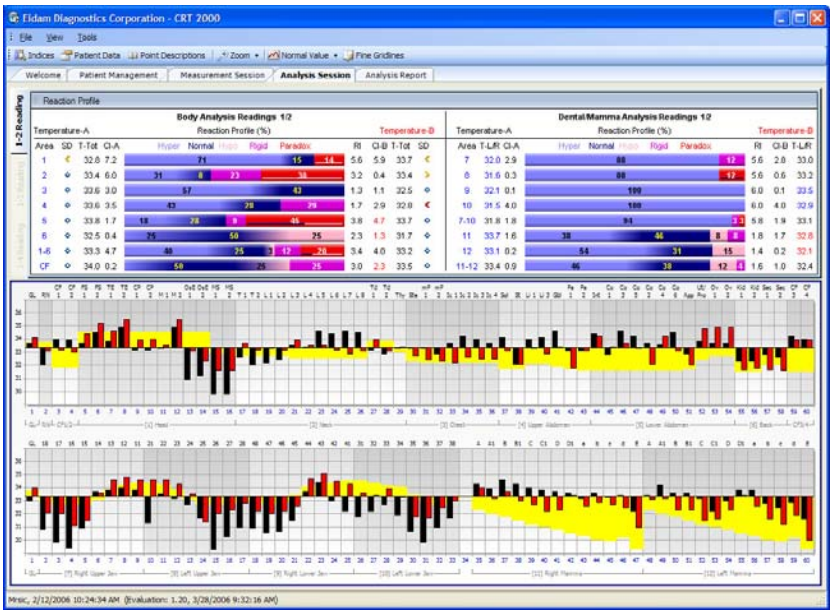
To send the session to the Server for analysis, click Load Analysis on the Toolbar.

The following window prompt will display:


Server Analysis
The CRT is ready to send a thermogram to Eidam Diagnostic's servers. Personal information about the patient, such as the patient's name, address, and contact information will not be transmitted. Do you wish to proceed?
Cancel
OK

After the server analysis is complete, the software will open to Thermogram Analysis.

Thermogram Analysis



This screen contains all of the measurement data and calculated indices necessary to perform an analysis of the patient. The Thermogram Analysis tab contains two panels:

1) The Reaction Profile above.
2) The Thermogram Display below.

Thermogram Display

The Thermogram is divided into the following areas:

Upper Thermogram	Lower Thermogram
1 – Head	7 – Right Upper Jaw
2 – Neck	8 – Left Upper Jaw
3 – Chest	9 – Right Lower Jaw
4 – Upper Abdomen	10 – Left Lower Jaw
5 – Lower Abdomen	11 – Right Mamma
6 – Back	12 – Left Mamma

Functions for use with the Thermogram Display

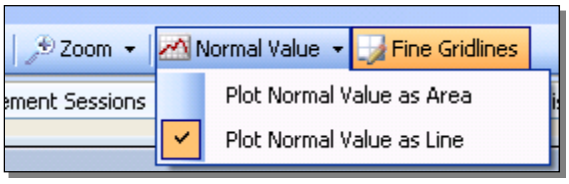
Toolbar functions change the appearance of the Thermogram:

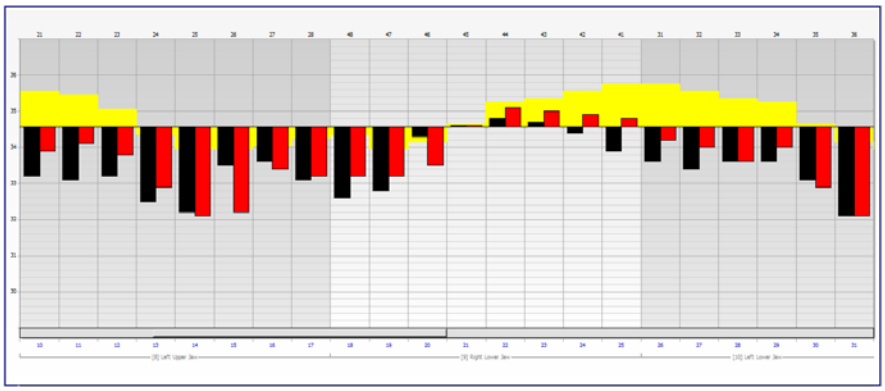
The **Zoom** function is a drop-down menu and allows for enlarged viewing of a portion of the Thermogram.

The **Normal Value** drop-down on the toolbar toggles the shaded yellow area between lines and solid areas.

The **Fine Gridlines** turns on or off additional higher resolution gridlines.

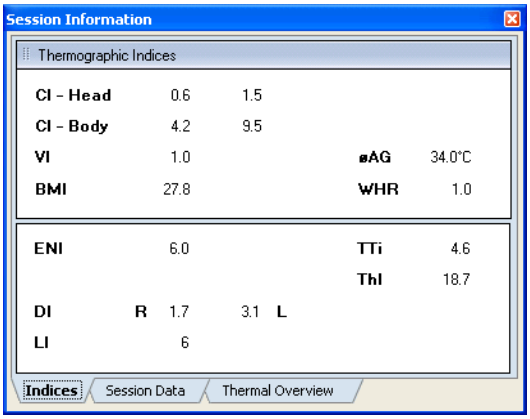
The following illustration demonstrates the Thermogram display with the following options selected: **Zoom Level 2, Bottom Thermogram only**, **Plot Normal Value as Line**, and **Fine Gridlines** enabled:



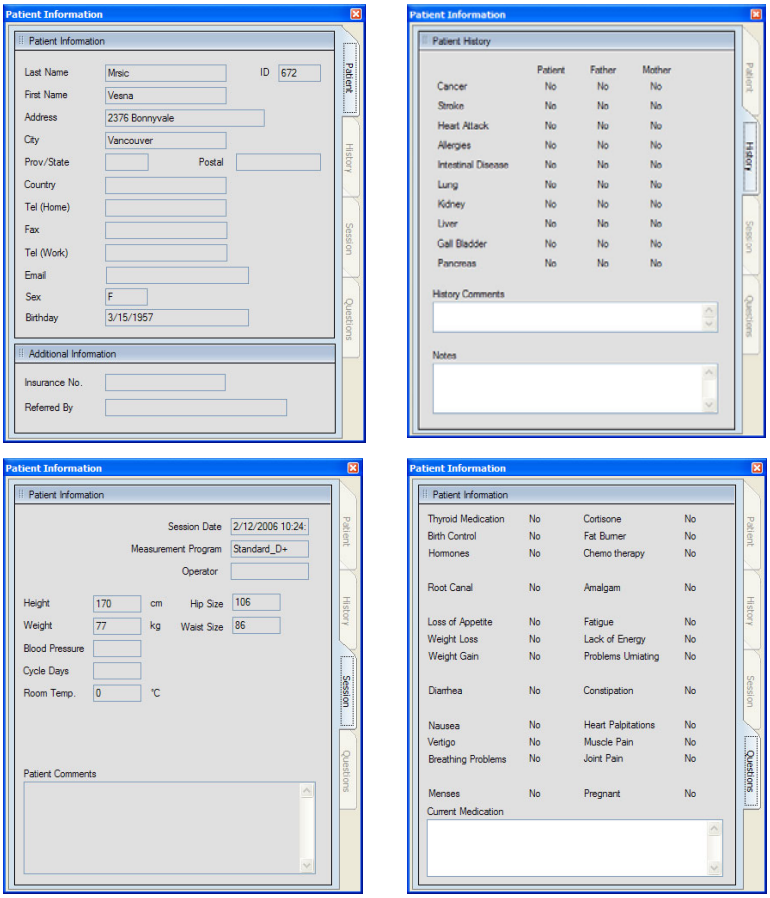


Other Toolbar Functions

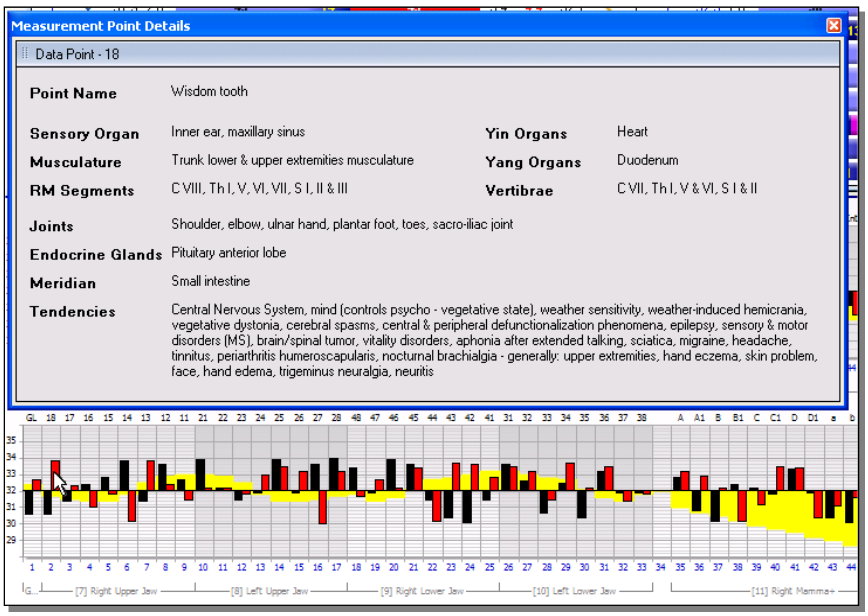
Indices: Will open the Session Information Window shown below:



Patient Data: Opens a window with four tabs, displaying patient information: Personal information, medical history with comments, measurements taken, questions related to complaints and/or pathological symptoms.

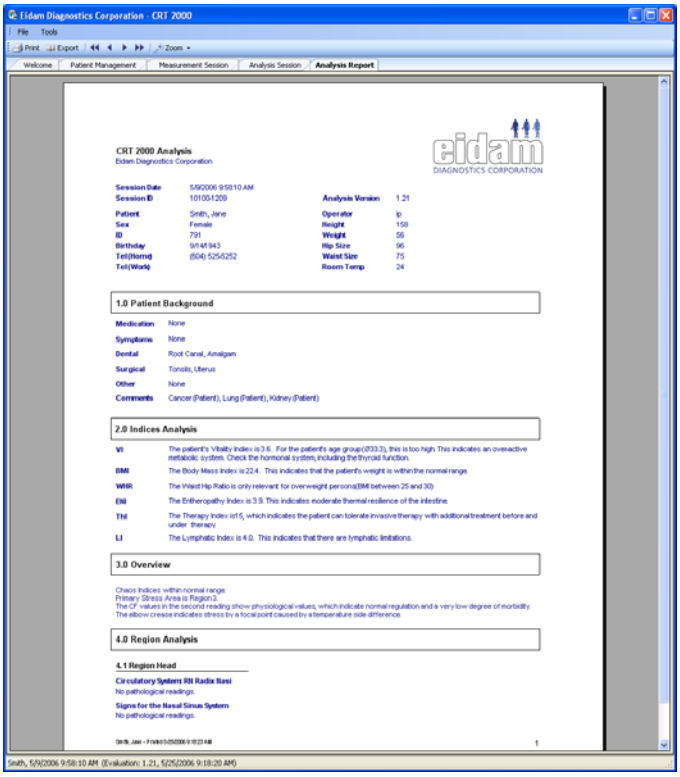


Point Descriptions: opens a pop-up window displaying *Measurement Point Details*. If the cursor is placed over a measurement in the Thermogram, the corresponding point description will be displayed


Measurement Point Details
Data Point - 18
Point Name Wisdom tooth
Sensory Organ Inner ear, maxillary sinus
Musculature Trunk lower & upper extremities musculature
RM Segments C VIII, Th I, V, VI, VII, S I, II & III
Yin Organs Heart
Yang Organs Duodenum
Vertibrae C VII, Th I, V & VI, S I & II
Joints Shoulder, elbow, ulnar hand, plantar foot, toes, sacro-iliac joint
Endocrine Glands Pituitary anterior lobe
Meridian Small intestine
Tendencies Central Nervous System, mind (controls psycho - vegetative state), weather sensitivity, weather-induced hemicrania, vegetative dystonia, cerebral spasms, central & peripheral defunctionalization phenomena, epilepsy, sensory & motor disorders (MS), brain/spinal tumor, vitality disorders, aphonia after extended talking, sciatica, migraine, headache, tinnitus, periarthritis humeroscapularis, nocturnal brachialgia - generally: upper extremities, hand eczema, skin problem, face, hand edema, trigeminus neuralgia, neuritis

Analysis Report

Once a Thermogram has been opened, the fifth tab, Analysis Report is available. This opens the server-based evaluation:


Eidam Diagnostics Corporation - CRT 2000
File Tools
Print Export Zoom
Welcome Patient Management Measurement Session Analysis Session Analysis Report
CRT 2000 Analysis
Eidam Diagnostics Corporation
eidam
DIAGNOSTICS CORPORATION
Session Date 5/9/2006 9:58:10 AM
Session ID 10100-1209
Analysis Version 1.21
Patient Smith, Jane
Sex Female
ID 791
Birthday 9/14/1943
Tel(Home) (604) 5256252
Tel(Work)
Operator ip
Height 159
Weight 56
Hip Size 96
Waist Size 75
Room Temp 24
1.0 Patient Background
Medication None
Symptoms None
Dental Root Canal, Amalgam
Surgical Tonsils, Uterus
Other None
Comments Cancer (Patient), Lung (Patient), Kidney (Patient)
2.0 Indices Analysis
VI The patient's Vitality Index is 3.6. For the patient's age group (2/33.3), this is too high. This indicates an overactive metabolic system. Check the hormonal system, including the thyroid function.
BMI The Body Mass Index is 22.4. This indicates that the patient's weight is within the normal range.
WHR The Waist Hip Ratio is only relevant for overweight persons (BMI between 25 and 30)
EII The Entheropathy Index is 3.9. This indicates moderate thermal resilience of the intestine.
THI The Therapy Index is 1.5, which indicates the patient can tolerate invasive therapy with additional treatment before and under therapy
LI The Lymphatic Index is 4.0. This indicates that there are lymphatic limitations.
3.0 Overview
Chaos Indices within normal range.
Primary Stress Area is Region3.
The CF values in the second reading show physiological values, which indicate normal regulation and a very low degree of morbidity.
The elbow crease indicates stress by a focal point caused by a temperature side difference.
4.0 Region Analysis
4.1 Region Head
Circulatory System RN Radix Nasi
No pathological readings.
Signs for the Nasal Sinus System
No pathological readings.
Smith, 5/9/2006 9:58:10 AM (Evaluation: 1.21, 5/25/2006 9:18:20 AM)

This represents a standardized, server-based evaluation of the data. Note that on the top-right corner of the evaluation, the report reads, “Analysis Version”. As new server interpretation methods become available, it is possible to re-submit data for evaluation.

Technical Specifications

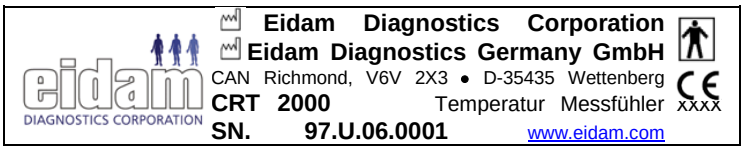
General

Weight:	8 kg
Dimensions:	105 x 325 x 430 mm
Voltage Input:	100 - 240 V AC +/- 10 %
Power Consumption:	180VA
Electrical Safety	This device conforms to the norm: VDE 0750, IEC 601-1 Class I with Measurement Function according to EC-Directive 93/42/EWG
Electromagnetic Compliance (EMC) according to EN 60601-1-2 and EN 794-3:	
– Noise suppression	EN 55011
– Interference Resistance	EN 61000 – 4 – 2 to 3

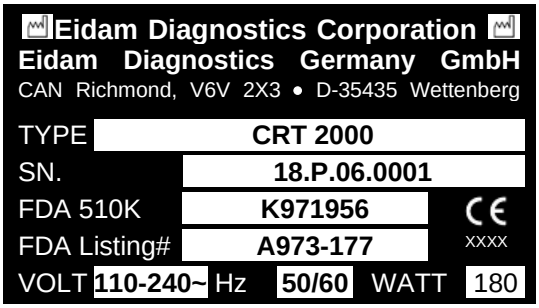
Temperature Measurement

Measurement Range:	26.0°C – 38.0°C
Measurement error:	+/-0.1°C when the Sensor tip is immersed in a water bath.

Sensor Label



Base Unit Label



Environmental Temperatures

Operating Temperature

The CRT sensor will operate in temperatures between 10°C and 40°C. If the CRT-2000 has been exposed to temperatures under 0°C, an acclimitisation phase is necessary.

CRT Measurement Sessions are only valid when the room temperature is stable and between 20°C and 24°C. Please refer to the Technician's Handbook for other measurement criteria.

Storage Temperature

The CRT-2000 can be stored at temperatures between -20° and +60°C.

Electromagnetic Compatibility (EMC)

Electromagnetic compatibility with surrounding devices should be assessed when using the CRT 2000®. An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the CRT 2000® according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2).

The CRT 2000® should not be used adjacent to, or stacked on top of other equipment. If the CRT 2000® must be used adjacent to or stacked on top of other equipment, verify that the CRT 2000® operates in an acceptable manner in the configuration in which it will be used.

The CRT 2000® will not malfunction when used with electrosurgical equipment. Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment (see Table on page **Error! Bookmark not defined.**)

Reducing Electromagnetic Interference

The CRT 2000® and accessories may become sensitive to interference from other RF energy sources including power lines. RF energy sources include

other medical devices, wireless devices, information technology equipment, and radio/television transmission. Should interference be encountered, as demonstrated by releasing measurments without touching the skin or jitter on the screen, attempt to locate the source by assessing:

- if the interference is intermittent or constant?
- does the interference occur only in certain locations?
- does the interference occur only when in close proximity to certain medical devices?

Once the source of the interference is located, attempt to attenuate the EMC coupling path by distancing the CRT 2000® from the source of the interference as much as possible. If further assistance is needed, contact the Support of Eidam.

Electromagentic Emissions

Guidance and Manufacturer's Declaration – Electromagentic Emissions		
The CRT 2000® is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the CRT 2000® should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment: guidance**
RF Emissions CISPR 11	Group 1	The CRT 2000® uses RF energy only for its internal function. Therefore, its RF emissions are very low are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The CRT 2000® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class D	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The CRT 2000® is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the CRT 2000® should assure that it is used in such an environment.			
Emissions Test	**Compliance**	**Compliance Level**	**Electromagnetic Environment: guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply line +/- 1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/-2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines	< 5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T)	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CRT 2000® required continued operation during power mains interruptions and to avoid loss of data, it is

IEC 61000-4-11	for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T for 5 seconds		recommended that the CRT 2000® be powered from an uninterruptable power supply.
Power frequency (50./60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The CRT 2000® is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the CRT 2000® should assure that it is used in such an environment.

Emissions Test	**Compliance**	**Compliance Level**	**Electromagnetic Environment: guidance**
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	Complies	Portable and mobile RF communi-cations equipment should be used no closer to any part of the CRT 2000®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = \left[\frac{3,5}{3V_{eff}}\right]\sqrt{P}$ $d = \left[\frac{3,5}{3V/m}\right]\sqrt{P}$ 80MHz to 800MHz $d = \left[\frac{7}{3V/m}\right]\sqrt{P}$ 800MHz to 2,5GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	Complies	

Note1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects, and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CRT 2000® is used exceeds the applicable RF compliance level above, the CRT 2000® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CRT 2000®.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the CRT 2000®

The CRT 2000® is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CRT 2000® can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CRT 2000® as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter (m)**	
	150 kHz to 800 MHz $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,1 m	0,2 m
0,1	0,4 m	0,7 m
1	1,2 m	2,3 m
10	3,8 m	7,3 m
100	12 m	23 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.

Device Safety Inspection

Eidam recommends that safety and functional inspections of the CRT 2000 Thermographic System be performed only by Eidam authorized CRT 2000 Service Centers. These Inspections must be conducted by certified service personnel, as improper inspections may fail to identify safety issues, or damage the equipment and void product warranty.

The Safety Inspection is a mandatory part of every service cycle. It Includes:

- Complete visual inspection
- Equipment Grounding Conductor Test (DIN EN 60601-1:1990)
- Leakage Current Measurement Test (DIN EN 60601-1:1990)
- Functional Test

Eidam's authorized service centers will complete these tests free of charge for product under Eidam's warranty or service agreement.

Metrological Inspection

This inspection ensures that the CRT Sensor is operating within its specification.

Eidam recommends that Metrological Inspections of the CRT 2000 Thermographic System be performed only by Eidam authorized CRT 2000 Service Centers. These Inspections must be conducted by certified service personnel, as improper inspections may fail to identify safety issues, or damage the equipment and void product warranty. Appropriate measurement and testing equipment are necessary for conducting the tests.

The accuracy of the metrological equipment and test environment must be a minimum of three times the specification accuracy of the device under test. Metrological testing to assess the maximum error must be conducted by qualified personnel in line with the regulations of the country within which the equipment is used.

Eidam, at a minimum, uses German regulations as its benchmark for such requirements and as such follows the “Guide to metrological controls of medical devices having a measurement function”, published by Physikalisch-Technischen Bundesanstalt, Germany (current revision: 6 September 2001). In Germany, “Persons conducting a metrological inspection must report this to the responsible bureau before beginning the inspection” (§11, Nr. 5, MPBetreibV).

Eidam’s authorized service centers will complete these tests free of charge for product covered under Eidam’s warranty or service agreement.

Frequently Asked Questions

CRT 2000 Frequently Asked Questions

Q. The software says that the server doesn't recognize my client license information. When I click Retry, it shows my customer ID as "000000". What do I do?

A. This occurs when there is a significant software upgrade. Please re-enter the serial number from the left side panel of the CRT Core Unit.

Q. How do I update my CRT to the latest software?

A. Each time you restart the CRT software or send a Thermogram for analysis, the CRT checks for software updates. If there is a software update, you will be prompted, and guided through the automatic update process

Q. How do I back up my data?

A. You can do this by clicking the Backup button from the Welcome screen, or by manually copying the database file from the data directory to a backup device of your choice (network, memory stick, or USB Hard Drive for example).

The database file resides, by default, in:

C:\Program Files\Eidam Diagnostics Corporation\CRT 2000 Thermographic System\Data

It is named either crt.mdb or crt.edb.

Q. Can I export the Analysis Report?

A. Yes, from the Analysis Report tab, click the Export Button. You will be offered a variety of formats, including Microsoft Word and Microsoft Excel.

Q. Can I read another practitioner's database?

A. Yes. Have them send you the database file from their Data directory. Copy this into a new folder on your hard drive, and open it from the Welcome screen by clicking File -> Open.

Q. Can I share with another practitioner just one or a few records, instead of my entire database?

A. Absolutely. From Patient Management, select a session and click File/Export. Follow the dialog box, and an XML file will be created that will allow another CRT 2000 owner to open it, by selecting File/Import from their Patient Management screen.

Q. How can I delete a patient who has session data?

A. If you truly wish to delete the patient, you will need to first delete all of their measurement sessions.

Q. How do I resubmit measurement data to the server?

A. From the Patient Management screen, select a measurement session, right click, and then left click **Resubmit Session**.

Q: ***How do I install a printer?***

A: Copy all printer drivers from the CD that came with the printer to a USB memory key. Insert the USB memory key into an available USB slot on your CRT 2000® Core Unit, and install printer drivers as per the instructions provided with your printer.

You may also choose to download the driver files from the printer manufacturer's website and install it directly on the CRT 2000® Core u

Appendix

Glossary

CRT 2000® Thermographic System.
The CRT 2000® Thermographic System includes the CRT Core Unit, CRT Sensor, CRT Display, CRT Measurement and Analysis Software, and CRT Server-based analysis service.

CRT Core Unit.
This is the computer system to which the CRT Sensor and Display connect to. It must be calibrated and checked for safety regularly.

CRT Core Unit LCD.
The CRT Core Unit LCD is the small backlit LCD that displays sensor status. It is located on the front left of the CRT Core Unit.

CRT Display.
This refers to the widescreen display.

CRT Measurement and Analysis Software.
The CRT Measurement and Analysis Software is the software program that is controls the CRT Thermographic System, allowing you to take measurements and read results.

CRT Sensor.
This is the measurement probe included with the CRT 2000® Thermographic System. It must be calibrated regularly.

Measurement Session.
This refers to a measurement session, which includes the recording of a patient's personal data and history, their first reading, a cooling period, and their second reading.

Measurement Set.
Each Measurement Session contains at least two sets of measurements. These are each referred to as a Measurement Set.

Support

Technical Support

For technical support please contact Eidam Diagnostics:

International

EIDAM Diagonstics Corporation
114-11120 Horseshoe Way
Richmond, BC V7A 5H7
Canada

Tel.: +1.604.304-6006
Fax: +1.604.304-6007

Toll Free North America: 1-866-798-4CRT(4278)

German Language 1-604-209-5085

Email: info@eidam.com
Internet: www.eidam.com

140-11120 Horseshoe Way
Richmond, BC V7A 5H7
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Tel 1 604 304 6006
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